REMARKS

In an Office Action dated January 15, 2008, claims 1 - 17 are pending and all claims stand rejected. Claims 3, 10, 16 have been cancelled from the present application. Claims 1, 2, 4 - 9, 11 - 15 and 17 are currently pending.

The Examiner required a new title. A new title is provided.

Nonstatutory obviousness-type double patenting

Claims 1 - 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 16 of U.S. Patent No. 6, 113, 920 in view of Rudnic et al. Applicants respectfully disagree. Claims 3, 10 and 16 have been cancelled from the present application. Therefore, the rejection is moot as to claims 3, 10 and 16. Claims 1, 2, and 15 have been amended. Neither reference discloses the specific pharmaceutical composition of a once daily immediate release formulation of zidovudine together with a sustained release formulation of lamivudine and zidovudine for once daily administration. Furthermore, Rudnic et al is not enabling for the preparation of a composition containing multiple antiviral drugs in general, and lamivudine and zidovudine in particular, formulated together. The examples of Rudnic are directed to formulations containing a single antiviral drug. The compositions of the present invention provide for an immediate release of zidovudine and lamivudine for the initial release period, thereby ensuring safey in administering the drugs followed by a controlled release of zidovudine in the small intestines to maximize absorption in that portion of the gastrointestinal tract, because the colonic absorption of zidovudine is very low (specification at page 5).

Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4 - 9, 11 - 15 and 17 on the ground of nonstatutory obviousness-type double patenting.

35 U.S.C. § 112, first paragraph

Claims 1 - 17 are rejected under 35 U.S.C. § 112, first paragraph. Claims 3, 10 and 16 have been cancelled from the present application. Therefore, the rejection is moot as to claims 3, 10 and 16. Claims 1 and 2 have been amended to recite salts. Support for the amendment to claims 1 and 2 may be found in the specification at page

4. Claims 4 - 9, 11 - 14 and 17 depend from amended claims 1 or 2. Claim 15 has been amended to delete derivative language. Claim 14 has been amended to recite treatment of an HIV infection in a human. Support for the amendment to claim 14 may be found in the specification at page 11.

Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4 - 9, 11 - 15 and 17 under 35 U.S.C. § 112, first paragraph.

35 U.S.C. § 112, second paragraph

Claim 3 is rejected under 35 U.S.C. § 112, second paragraph. Claim 3 has been cancelled from the present application. Therefore, the rejection is moot as to claim 3.

Claim 5 is rejected under 35 U.S.C. § 112, second paragraph. Claim 5 has been amended to recite hydroxypropylmethylcellulose of different viscosities. Support for the amendment to claim 5 may be found in the specification at page 7 - 8 and Example 1.

Applicants respectfully request withdrawal of the rejection of claim 5 under 35 U.S.C. § 112, second paragraph.

35 U.S.C. § 103 (a)

Claims 1 - 17 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Rudnic in view of Cameron. Claims 3, 10 and 16 have been cancelled from the present application. Therefore, the rejection is moot as to claims 3, 10 and 16. Claims 1, 2 and 15 have been amended to recite compositions for once daily administration. Support for the amendment to claims 1, 2, and 15 may be found in the specification at page 13 and claim 10 as originally filed. Rudnic does not disclose the present invention of an immediate release formulation of zidovudine together with a sustained release formulation of lamivudine and zidovudine. Furthermore, Rudnic et al is not enabling for the preparation of a composition containing antivirals in general, and lamivudine and zidovudine in particular, formulated together. The examples of Rudnic are directed to formulations containing a single antiviral. Rudnic is not enabling for the preparation of a once daily formulation of zidovudine and lamivudine that allows safety and maximizes absorption of zidovudine. The short half-life of zidovudine in the blood and zidovudine's preferential absorption on the upper part of the gastrointestinal tract were thought to preclude once daily dosing (specification at page 3).

Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4 - 9, 11 - 15 and 17 under 35 U.S.C. § 103 (a).

Applicants hereby request a 3-month extension of time to extend the response period up to and including July 15, 2008. The Commissioner is hereby authorized to charge such fees and any other fees required or credit any overpayment to Deposit Account No. 07-1392.

It is respectfully submitted that the present application is in condition for examination. An early consideration and notice of allowance are earnestly solicited.

Respectfully submitted,

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